K110748

510(k) Summary of Safety and Effectiveness

February 1, 2012

FEB 15 2012

- **Applicant** — Olympus Winter & Ibe GmbH
  Kuehnstrasse 61 * 22045 Hamburg * Germany
  Establishment Registration No: 9610773

- **Official Correspondent** — Stacy Abbatiello Kluesner, M.S., RAC
  Regulatory Affairs & Quality Assurance
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- **Manufacturer** — Olympus Winter and Ibe GmbH
  Kuehnstrasse 61 * 22045 Hamburg * Germany
  Establishment Registration No.: 9610773

- **Device Trade Name:** — Olympus Winter & Ibe Instrument Tray WA05991A; abbreviated hereinafter as *Olympus Instrument Tray*

- **Common Name:** — Sterilization Wrap Container, Tray, Cassette & other Accessories

- **Regulation Number:** — 21 CFR 880.6850

- **Regulation Name:** — Sterilization Wrap

- **Regulatory Class:** — II

- **Product Code:** — KCT

- **Classification Panel:** — General Hospital

- **Performance Standards:** — None established

- **Predicate Devices:**
  - **K092682** Gyrus ACMI® Flexible Endoscope Storage-Sterilization Trays
  - **K033222** Olympus Sterilization Trays

- **Intended Use:**

This instrument tray is intended to be used to enclose and protect Olympus flexible endoscopes during sterilization. The instrument tray is designed to hold one endoscope at a time and is to be used in conjunction with an FDA cleared sterilization wrap for ethylene oxide sterilization. The instrument tray is an optional accessory to the Olympus endoscopes for which it is designed. Maintenance of sterility depends on the sterilization wrap, not on the instrument tray.
This instrument tray is indicated for ethylene oxide sterilization of only compatible Olympus endoscopes. For compatible endoscopes, refer to the table below "Compatible Olympus Endoscopes".

Compatible Olympus Endoscopes are:

CHF-CB30L	CYF-V2R	ENF-V3	LF-DP
CHF-CB30S	CYF-VA2	ENF-VQ	LF-GP
CHF-P20	CYF-VH	ENF-VT2	LF-P
CHF-P60	CYF-VHA	ENF-XP	LF-TP
CHF-XP20	CYF-VHR	ENF-VH	LF-V
CHF-V	ENF-GP	HYF-1T	URF-P5
CYF-5	ENF-P4	HYF-V	URF-V
CYF-5A	ENF-T3	HYF-XP	
CYF-V2	ENF-V2	LF-2	

Worst case dimension:
The endoscope URF-P5 offers the most challenging dimensions in regards to maximum length (835 mm), minimum inner diameter (1.2 mm) and number of lumen (1).

Ethylene oxide sterilization parameters:
In chamber conditioning
Temperature..... 55 °C
Humidity.....65 %
Vacuum set point.....8.96 kPa (1.3 psia)
Time..... 60 minutes
Exposure
Temperature..... 55 °C
Humidity.....65 %
Sterilization gas.....100 % ethylene oxide
Ethylene oxide gas concentration..... 735 mg/l
Exposure time..... 60 minutes
Aeration
Temperature..... 50 °C
Time.....12 hours

■ **Product Description:**

Tray	Item no.	Compatible endoscopes
Olympus Instrument Tray	WA05991A	Olympus Flexible Endoscopes of the CHF, CYF, ENF, HYF, LF, and URF series
Feature	The Olympus Instrument Tray is comprised of plastic lids and bottoms that contain numerous large holes (approximately 7mm in diameter) that permit ready ingress and egress of sterilization gases. The trays are designed to provide protection from physical damage to the flexible endoscope during sterilization and storage.	
Intended Use	Provided above.	
Material	The trays are constructed of biocompatible RADEL-R. Radel-R is a polyphenylsulfone plastic that is widely used in medical devices. Radel-R meets the requirements for biocompatibility pursuant to ISO-10993 and is compatible with EtO sterilization.	
Patient Contact	The trays do not contact the patient	
Sterilization modality	EtO	
Dimensions	531mm (L) x 255mm (W) x 86mm (D)	

■ **Performance Data**:

Validation of "Worst-Case" Challenges of the Instrument Tray:
Validation was performed to assess the worst case component load and the ability of ethylene oxide to penetrate and aerate from the surfaces and silicon holders of the Instrument Tray. The PCDs (process challenge devices) were placed in the trays and inoculated with FDA cleared biological indicator organisms, and chemical indicators were placed. The trays were wrapped with two layers of FDA approved sterilization wrap (Kimguard KC600; K082554) and placed into ethylene oxide sterilizer for processing. The system was sterilized successfully in a 30 minute half cycle demonstrating 6 log reduction capability (SAL of 10-6). Test systems were exposed to 60 minute full cycles and ethylene oxide residual testing was performed, with a 12 hour aeration time. Pursuant to ISO10993-7, residual concentrations of EO and ECH were all within acceptable limits. Therefore the instrument tray is effectively sterilized when the worst case components are loaded and the level of remaining residuals was found to be acceptable.

Validation of 'Worst-Case" Endoscope in the Instrument Tray:
Validation was also performed to assess the worst case endoscope (URF-P5) loaded into the instrument tray. This testing assessed the ability of ethylene oxide to penetrate the worst case endoscope features (lumen length and diameter) and the level of residuals remaining. Validation was performed with FDA cleared accessories, including biological indications, sterilization wrap (Kimguard KC600; K082554) and ethylene oxide sterilizer. The endoscopes were sterilized successfully in a 30 minute half cycle demonstrating 6 log reduction capability (SAL of 10-6). The endoscopes were exposed for full cycles and all ethylene oxide residual concentrations of EO and ECG were all within acceptable limits. Therefore, the Instrument Tray was found to not hinder sterilization and aeration of the worst-case endoscope.

Risk analysis was carried out in accordance with established in-house acceptance criteria based on ISO 14971:2007. Other standards applied to the design of this device include ANSI/AMMI ST33-1996, AAMI / ANSI / ISO 11135-1, AAMI / ANSI / ISO 10993-1, AAMI / ANSI / ISO 10993-7, and AAMI/ ANSI ST77:2006.

■ **Technological Characteristics and Substantial Equivalence:**

The Olympus Winter & Ibe GmbH Instrument Tray is composed of the same materials, constructed the same and uses the same design philosophy as the general hospital trays sold by Gyrus ACMI FGT Endoscopes Storage/Sterilization trays (K092682) and Olympus (K033222). In contrast to the Olympus Sterilization Trays (K033222), the *Olympus Instrument Tray* is only indicated for EtO sterilization as is the Gyrus ACMI FGT Storage/Sterilization Tray (K092686).

- **Conclusion:**
  In summary, the Olympus Instrument Tray is substantially equivalent to the predicate devices and raises no new concerns of safety or efficacy when compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

Olympus Winter & Ibe GmbH
C/O Stacy A. Kluesner, M.S., RAC
Regulatory Affairs & Quality Assurance
Olympus America, Inc.
3500 Corporate Parkway
Center Valley, Pennsylvania 18034

FEB 15 2012

Re: K110748
Trade/Device Name: Olympus Instrument tray
Regulation Number: 21 CFR 880.6850
Regulation Name: Sterilization Wrap
Regulatory Class: II
Product Code: KCT
Dated: February 3, 2012
Received: February 8, 2012

Dear Ms. Kluesner:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

for Anthony D. Watson

Anthony D. Watson, B.S., M.S., M.B.A.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number: K110748
Device Name: Olympus Instrument tray
Model Numbers: WA05991A

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CHF-P60	CYF-VHA	ENF-XP	LF-TP
CHF-XP20	CYF-VHR	ENF-VH	LF-V
CHF-V	ENF-GP	HYF-1T	URF-P5
CYF-5	ENF-P4	HYF-V	URF-V
CYF-5A	ENF-T3	HYF-XP	
CYF-V2	ENF-V2	LF-2	

Prescription Use_____ AND/OR Over-The-Counter Use__✓__
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for Anthony D. Watson

(Division Sign-Off)
Division of Anesthesiology, General Hospital
Infection Control, Dental Devices

510(k) Number: K110748

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Concurrence of CDRH, Office of Device Evaluation (ODE)

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